#13 NW

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Whitsett, et al.	) Group Art Unit 1653
Appl. No.	:	09/558,576	)
Filed	:	April 26, 2000	)
For	:	SURFACTANT PROTEIN D FOR THE PREVENTION AND DIAGNOSIS OF PULMONARY EMPHYSEMA	)
Examiner	:	Schnizer, H.	)

DECLARATION UNDER 35 CFR §1.132

1. I, Jeffrey Whitsett, M.D. am an inventor on the above-identified patent application and am familiar with the specification and prosecution history.

2. I have extensive experience in the field of immunology and molecular biology as evidenced by my attached curriculum vitae (Exhibit A).

3. The previous experiments by Van Iwaarden, et al. as referenced in Johansson, et al. (J. Eur. Respir. 1994, Vol. 7, pages 372-391) and as referred to by the Examiner, show that SP-D increased superoxide production in alveolar macrophages *in vitro*. However, a clinician would not be motivated to make a pharmaceutical composition comprising SP-D to treat inflammatory diseases of the lung with this knowledge. This is because, increased superoxide production correlates with increased inflammation. As discussed below, this would actually lead one of skill in the art not to employ SP-D as a pharmaceutical composition.

4. A clinician would be motivated to treat lung disease with a pharmaceutical which decreased inflammation. This is because the pathogenesis of lung diseases, including those lung diseases which are caused by pathogens (both bacterial or viral) and those which are not caused by pathogens (or are caused after the pathogen is killed or cleared - which occurs very rapidly) is due predominantly to uncontrolled inflammation.

For example, lung diseases caused by bacteria are currently treated with antibiotics which rapidly and effectively clear the lung of the infectious agent. However, the inflammation in acute and chronic lung diseases often continues after clearance of the pathogen due to the host inflammatory response. The pathogenesis of lung diseases such as emphysema and chronic obstructive lung disease is predominantly due to inflammatory processes and not directly related to the ongoing presence of the pathogen or its products. The pathogenesis of lung inflammation or chronic lung disease caused by viruses is often due predominantly to inflammation. The viruses are generally killed and cleared rapidly after a certain period of time, but the symptoms and pathogenesis of lung disease continues as a result of the inflammation.

5. Further, the experiments in Yoshida et al. Journal of Immunology, 166, 75, 14, 2001, were done under my control and all statements in the article are accurate. These experiments were done *in vivo* in a mouse model and show that, surprisingly, SP-D does not increase inflammation as shown in the *in vitro* experiments of Van Iwaarden, et al. In fact, the experiments as well as the data with the knockout mouse in the present patent application show that SP-D actually decreases inflammation, making it a preferred treatment for infectious and non-infectious lung diseases (see page 20, Example 7). It is likely that in the experiments by Van Iwaarden, et al. the SP-D was contaminated with an inflammatory substance such as lipopolysaccharide (LPS), a bacterial endotoxin. This would lead to the incorrect results showing that SP-D was pro-inflammatory, when our results correctly show that SP-D is anti-inflammatory.

6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patent issuing therefrom.

Dated: 2/26/02 By: _____
Jeffrey Whitsett

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CURRICULUM VITAE

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PERSONAL DATA

Born: May 19, 1947, Cleveland, OH USA
Married: Four children - Sarah 1976, Anna 1979, Margaret 1982, David 1985
Wife: Dorinda Dew

UNDERGRADUATE EDUCATION	1969	Colgate University, Hamilton, NY, B.A. Chemistry
MEDICAL EDUCATION	1973	Columbia University, New York, NY, M.D.
CLINICAL TRAINING	1973-1974	Internship - Mt. Sinai Hospital, New York, NY
	1974-1976	Residency - Mt. Sinai Hospital, New York, NY
POSTGRADUATE TRAINING	1976-1977	Neonatology Fellowship - Children's Hospital Medical Center, University of Cincinnati College of Medicine

ACADEMIC

1995	Director, Divisions of Neonatology and Pulmonary Biology
1994	Vice Chairperson, Department of Pediatrics, Children's Hospital Medical Center
1988	Director, Division of Pulmonary Biology
1985	Professor of Pediatrics, and Pharmacology and Cell Biophysics, University of Cincinnati College of Medicine
1984	Director Research, Newborn Division
1981	Associate Professor of Pediatrics
1981	Research Associate, Division of Cell Biology, Institute for Developmental Research
1978	Assistant Professor of Pediatrics
1977	Instructor in Research Pediatrics, University of Cincinnati

HONORS

1969	High Honors in Chemistry, Magna Cum Laude, Colgate University, Phi Beta Kappa
1973	Community Medicine Award, Columbia University
1979	Certified by American Board of Pediatric Examiners
1979	Board Certified Neonatology
1981	Sigma Zi Research Award, University of Cincinnati
1987	American Society for Clinical Investigation
1987-92	Member, NIH Study Section, Human Embryology and Development
1988	E. Mead Johnson Award
1992	Council Member, Society Pediatric Research
1992	NIH Merit Award
1993	Chair, North American Cystic Fibrosis Meeting
1994	1st Julius Comroe Award in Pulmonary Research, FASEB
1995	Amberson Lecture Award - American Thoracic Society
1993-1996	Review Board - Basil O'Conner, March of Dimes
	William Cooper Procter Award - The Children's Hospital, Cincinnati
2001	Daniel Drake Award - The University of Cincinnati

LICENSURE Ohio, Kentucky

SOCIETIES

Society for Pediatric Research 1980
American Society Clinical Investigation 1986
American Society of Cell Biologists 1989
American Society for Clinical Investigation, Inc., Member of the Editorial Committee

COMMUNITY SERVICE

Chairman, Outreach Committee, Church of the Redeemer, Hyde Park, 1983-1986
Member of Medical Care for the Homeless Committee, 1984
Medical Committee, Walk-in-Center, Cincinnati, OH 1983-1986
Member Church Choir, Church of Redeemer, 1987-1986
Member Cincinnati Choral Society, 1982-1983
Board Member, Health Initiative

CLINICAL APPOINTMENTS

Children's Hospital Medical Center, Cincinnati, OH
University Hospital, Cincinnati, OH
Jewish Hospital, Cincinnati, OH
St. Elizabeth Hospital, Edgewood, KY
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TRAINEES (graduate and postgraduate) past and present:

John Moore, M.D.
Akihiko Noguchi, M.D.
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Gary Ross, Ph.D.
Bryan Ohning, M.D., Ph.D.
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GRADUATE STUDENTS

Michael A. O'Reilly, Ph.D. - Developmental Biology
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Diane Vorbroker - Ph.D. Student
Kwon-Sik Park - Developmental Biology
Zvjezdana (Stella) Sever - Ph.D. Student
Jackie Huffman - Ph.D. Student
Xin Zeng - Ph.D. Student
Cong Liu - Developmental Biology
Paul Reynolds - Developmental Biology
Huajing Wan - Cell Biology

PATENTS

Surfactant protein-C US patent# 5,013,720
5,387,746
Nucleic Acid Sequences Controlling Lung Cell-Specific Gene Expression, US patent# 5,976,873

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ARTICLES

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3. Whitsett, J.A., Johnson, C. and Hawkins, K.: Differences in the localization of adenylate cyclase and insulin receptors in the human placenta. Am. J. Obstet. Gynecol. 133:204-207, 1979.

4. Whitsett, J.A. and Johnson, C.: Adenylate cyclase from human decidua parietalis. Am. J. Obstet. Gynecol. 133:479-483, 1979.

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13. Whitsett, J.A. and Darovec-Beckerman, C.: Developmental aspects of ß-Adrenergic receptors and catecholamine-sensitive adenylate cyclase in rat myocardium. Pediatr. Res. 15:1363-1369, 1981.

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